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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,080	10/08/2004	J. Phillip Bowen	B40-002	3420

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EXAMINER	
GULLEDGE, BRIAN M	

ART UNIT	PAPER NUMBER
4161	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,080	BOWEN ET AL.	
	Examiner	Art Unit	
	Brian Gulledge	4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,15,38 and 39* is/are pending in the application.

4a) Of the above claim(s) *3,4 and 6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,7,8,15,38 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/21/04; 12/04/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Change of Examiner

This application has been reassigned from Joseph Kudla to Brian Gulledge for the remainder of its prosecution. Applicant is advised that future communications should be directed to Brian Gulledge, who can be contacted at 571-270-5756, Monday–Thursday from 6:00 am until 3:00 pm.

Status of the Claims

Claims 1-8, 15, and 38-39 are pending. Claims 1-2, 5, 7-8, 15, and 38-39 are the subject of this Office Action, and claims 3-4 and 6 are withdrawn. This is the first Office Action on the merits of the claims.

Priority

The earliest effective U.S. filing date afforded the instantly claimed invention has been determined to be January 25, 2002, the filing date of the provisional application 60/351,880.

Election/Restrictions

Applicant's election with traverse of Invention I, "cutaneous malignancy" as the species for the type of cancer, and "Solenospin A" for the compound in the reply filed on March 28, 2008 is acknowledged. The traversal is on the ground(s) that no evidence of a serious search

burden has been presented. This is not found persuasive because applicant is arguing an inappropriate restriction standard.

The Examiner has properly applied the standard of unity of invention that governs this application. This application is a national stage filing of a PCT application under 35 USC 371. 35 USC 372 (a)(2) provides authority to evaluate unity of invention:

> [T]he Director may cause the question of unity of invention to be reexamined under section 121 of this title, within the scope of the requirements of the treaty and the Regulations;

As such, all claims of the application must be examined together as long as there is unity of invention as defined in Patent Cooperation Treaty Rule 13.2 and 37 CFR 1.475(a):

> An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Examiner has determined that the instant application lacks unity of invention because the inventions of Group I and II do not share a special technical feature; therefore, the instant application lacks unity of invention. Under these circumstances, restriction is proper as outlined in 37 CFR 1.499:

> If the examiner finds that a national stage application lacks unity of invention under § 1.475, the examiner may in an Office action require the applicant in the response to that action to elect the invention to which the claims shall be restricted. Such requirement may be made before any action on the merits but may be made at any time before the final action at the discretion of the examiner. Review of any such requirement is provided under §§ 1.143 and 1.144.

As such the restriction requirement is deemed proper and made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 15 recites that the tumor is selected from a group that, among the members recited, consists of lymphangiogenesis (line 4). Lymphangiogenesis is not a type of tumor, but rather a physiological process that forms lymphatic vessels. Consequently, it is unclear what is included in the recited group.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Rehmert (US Patent 4,910,209; issued March 20, 1990). Instant claim 1 recites a pharmaceutical composition in an oral dosage form, for administering to a mammal, which comprises a piperidine compound. This instant claim is anticipated by Rehmert, which discloses a method of treating animals by orally administering a piperidine alkaloid composition (column 1, lines 40-43). The primary piperidine alkaloid used is Solenopsin A (column 1, lines 61-65),

which reads on the instantly recited structure wherein R^1 for Solenopsin A is methyl (C_1) and R^2 is undecyl (C_{11}). The use of Solenopsin A by Rehmert also anticipates the limitations to the compound employed that are recited in instant claims 2 (R^1 and R^2 are C_1-C_{11}), instant claim 5 (R^1 and R^2 are straight-chained alkyl), and instant claim 7 (R^1 is methyl).

Claims 1, 8 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Goulet et al. (US Patent 5,849,764; issued December 15, 1998). Instant claim 8 recites a method of treating a cancer that comprises administering a composition according to instant claim 1. Goulet et al. anticipates this claim by disclosing compounds to treat breast cancer (column 2, lines 32-38). These compounds include piperidine derivatives such as 13JJ and 13KK (column 86), and the piperidine derivatives read on the compound recited in instant claim 1. Namely, there is a saturated linear C_3 (aryl)-substituted group and a saturated linear C_2 (aryl)-substituted group which read on R^1 and R^2, which are instantly recited to be limited to C_1 to C_{20} saturated linear substituted groups. Instant claim 15 further limits the tumor or cancer treated by the method of instant claim 8, one limitation being breast cancer. This limitation is anticipated by Goulet et al. and the disclosed use of the compounds to treat breast cancer (column 2, lines 32-38).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 8, 15, and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goulet et al. (US Patent 5,849,764; issued December 15, 1998) in view of Falk et al. (US Patent 6,147,059; issued November 14, 2000). Instant claims 38 and 39 further limit instant claims 8 and 15, respectively, by reciting that the cancer treated by the composition of instant claim 1 is cutaneous malignancy. Goulet et al teaches all of the limitations of instant claims 8 and 15 (see the above discussion), but does not disclose using the composition to treat cutaneous malignancy.

Falk et al. teaches a composition that treats disease conditions such as basal cell carcinoma (a type of cutaneous malignancy) and breast cancer by delivering drugs such as hyaluronic acid (column 1, lines 18-35).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have used the composition taught by Goulet et al., known for treating breast cancer with a piperidine compound, to treat basal cell carcinoma, one of several forms of cancer treated by the composition taught by Falk et al., because there is still a need for efficacious treatments of cutaneous malignancies.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 5 and 7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 9-10 of U.S. Patent No. 6,369,078. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method taught in claims 1 and 9-10 of the patent teach a method of using a composition comprising a carrier and a piperidine that reads on the instantly recited piperidine compound. The only difference is the patented claims recite a method of use, which includes the composition and use thereof, whereas the instant claims only recite the composition.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Gulledge whose telephone number is (571) 270-5756. The examiner can normally be reached on Monday-Thursday 6:00am - 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BMG

/Ashwin Mehta/
Primary Examiner, Technology Center 1600